

## **Summary of the Transition Committee Meeting January 15, 1998**

The Transition Committee of the National Environmental Laboratory Accreditation Conference (NELAC) met on Thursday, January 15, 1998, at 9 a.m. Eastern Standard Time (EST) as part of the Third NELAC Interim Meeting in Arlington, VA. The meeting was led by its chair, Dr. Charles Brokopp of the Utah Department of Health. A list of action items is given in Attachment A. A list of participants is given in Attachment B.

### **WELCOME AND INTRODUCTIONS**

Dr. Brokopp introduced the committee members and explained that the meeting, while following the prepared agenda, would be a very open meeting and questions would be welcomed. A discussion of the agenda items then ensued.

### **UPDATE ON THE APPROVAL OF ACCREDITING AUTHORITIES**

Letters and applications were sent to prospective accrediting authorities in October 1997. Originally, applications were to be returned by December 31, 1997, but that deadline has been extended to January 31, 1998. Applications will also be accepted after January 31, 1998, and will be processed in the order in which they are received.

Current State accrediting programs were surveyed prior to the July 1997 meeting in Dallas, TX and again prior to this Third Interim Meeting. The survey obtained information (see tabulation in Attachment C) on the proposed application date for each program, the number of laboratory surveyors in each program, the number of in-state and out-of-state laboratories currently certified, and the EPA programs for which the State intends to accredit laboratories.

Applications have already been received from Texas, Florida, and Idaho. Eighteen States indicated they will submit applications by January 31, 1998, and 10 States indicated they will submit applications by October 1998. All applications received by January 31, 1998, will be batched and evaluated for completeness by Ms. Jeanne Mourrain and her staff, with the estimated date for approval for this initial group of late Fall or early Winter 1998. It was reiterated that review of the applications of the first 18 States will be handled concurrently so that no individual State is flooded with applications because it is the first accrediting authority.

The States that have indicated they would request National Environmental Laboratory Accreditation Program (NELAP) recognition by January 31, 1998, are Arkansas, California, Colorado, Florida, Idaho, Illinois, Kansas, Nebraska, New Hampshire, New Jersey, New York, Ohio, Oregon, Pennsylvania, Texas, Utah, and Virginia. These 18 State programs currently employ 84 surveyors and accredit 3,401 in-state and 1,227 out-of-state laboratories. Of these 18 States, 15 intend to certify to Clean Water Act Standards, 14 to RCRA Standards, 8 to Clean Air Act Standards, 16 to the Safe Drinking Water Act Standards, and 11 to CERCLA Standards.

A participant asked what basis would be used to evaluate laboratories since the NELAC Standards are still in a state of flux. Ms. Mourrain, NELAP Director, stated that the Standards to be used are those approved in July 1997.

A participant asked what will happen to States that are still accrediting under old legislation. The Chapter 6 Standard is written so that it will not be possible for a State to become an accrediting authority unless it can accredit to NELAC Standards. An accrediting authority that currently has a program in place and whose only deficiency is that it does not have legislation and regulations in place will have until July 1, 2000, to bring its rules and statutes into compliance with the NELAC Standards.

When concern was raised regarding training of the assessors who will visit the first 18 States, Ms. Mourrain reported that EPA would convene a meeting to coordinate the informal training that will be made available by the Agency for its regional staffs, in order to maximize uniformity across those regions. States will be notified concerning regional EPA participation in the recognition of accrediting authorities.

There are programs in place that will receive NELAP recognition that do not have all rules in place during the first two years. Mr. John Anderson, chair of the Accrediting Authority Committee, stated that the way Chapter 6 is currently written, States that have an accrediting program in place could become NELAP-recognized before they have all rules in place during the first two years. The only acceptable NELAP deficiency would be legislation and/or regulations to make needed changes. About half the States would need to change their statutes, and about three-quarters of the States would need to update their rules.

A participant asked if accrediting authorities will be required to enter into fully reciprocal relationships with other accrediting authorities during the start-up period. The committee responded that reciprocity is the cornerstone of NELAC and that all accrediting authorities will be required to accept the terms of unconditional reciprocity. However, it was acknowledged that the term "reciprocity" creates problems for some States, and that alternative language would be discussed later in this meeting.

A question was raised concerning laboratories that receive accreditation from an accrediting authority that in turn does not come into full NELAP compliance by July 1, 2000. The committee responded that the laboratory's accreditation would remain valid for the duration of its accreditation period. If its accrediting authority was not fully NELAP-compliant by July 1, 2000, the laboratory would be required to apply for accreditation through another NELAP-compliant accrediting authority at the time for renewal.

## **SUPPLEMENTAL STATE REQUIREMENTS**

Section 1.9.2 from the NELAC Standards was read. Examples of differing State requirements were shown in an overhead by Dr. Brokopp. Requirements that may differ from State to State include detection/reporting limits, quality control (QC) sample frequency/acceptance criteria, varying methods for a given parameter, sample preservation, extraction methods, level/number of calibration standards, calculation procedures, concentration level of QC spikes, and the contents

of final reports. States should attempt to come to agreement on as many of these differences as possible. A laboratory's client can always impose different requirements on that laboratory than NELAP would require. If the laboratory's client is a State, the laboratory would have to be accredited for the method required by that State. An analogy was drawn by committee members between the NELAP accreditation process and driver's licensing in the United States. Each State may have its own specific requirements regarding operation of a motor vehicle in that State, and those requirements may differ from those of a neighboring State. A State may impose a fine for a failure to meet those requirements without actually revoking the license.

A participant asked about the situation in which a primary accrediting authority does not have authority for a specific method performed by a laboratory within that State. The committee responded that the laboratory would be required to get accreditation from another primary accrediting authority for that method.

## **ACCREDITATION OF OUT-OF-STATE LABORATORIES**

The term "reciprocity" seems to create problems for some States. A discussion occurred on possible alternative language, including "interstate recognition", "mutual recognition", and "recognition". The implied requirement of each of the first two terms is that if one State recognizes the accreditation of a second State, the second must recognize that of the first. This committee will seek the approval of the NELAC Board of Directors to change all occurrences of the term "reciprocity" in the NELAC Standards to the term "recognition."

A participant suggested that there may be other problems during the two-year grace period. An accrediting authority not meeting all the NELAC Standards might accredit a laboratory. That laboratory might then request to be accredited in another State. The secondary accrediting authority would be required to accept that laboratory's accreditation even though the primary accrediting authority is not in compliance with the Standards.

The audience was reminded that any reciprocal arrangement covers only NELAP requirements. The needs of a laboratory's client may well exceed those of NELAP.

A participant suggested that there should be a section outlining the enforcement requirements of primary accrediting authorities.

## **TRAINING OF LABORATORY INSPECTORS**

The assessor training manual prepared under contract to EPA was then discussed and as a result of discussion at the Interim meeting, will undergo extensive revision. Currently, the manual is contained as an appendix to Chapter 3 of the NELAC Standards. Revisions to the manual will continue, with all prepared materials to eventually be made available to private-sector organizations interested in developing assessor training and to laboratories interested in the standards to which they will be held accountable. EPA does not plan to provide any oversight of assessor training.

The question was raised as to the guidelines to be used by an assessor inspecting a laboratory for ISO Guide 25, 58, or 61 requirements. Ms. Mourrain stated that the requirements of those guides had been incorporated in Chapter 6 of the NELAC Standards and that Chapter 6 would provide the appropriate assessor guidelines.

It was agreed that accrediting authorities and EPA regional offices could offer in-house training for their assessors as long as they meet the guidance outlined in the NELAC Standards. In response to an inquiry about EPA (Cincinnati) NERL training, Ms. Mourrain replied that that particular training was not designed to cover NELAP requirements.

A concern was raised as to whether oversight of assessors was as important an issue as oversight of proficiency testing (PT) sample providers. A participant stated that the NELAC Standards require that assessor training programs be NELAP-approved. There was strong sentiment that there should be structured review/oversight of assessor training course content. It was agreed that the voiced concerns were legitimate and that the committee should consider the recommendation.

## **NON-NELAP ACCREDITATION SYSTEMS**

There may be states that want to run a two-tiered accreditation system. These States will continue to offer existing certification programs while applying for NELAP recognition and eventually accrediting those laboratories seeking NELAP accreditation. The existing programs might be continued in order to accommodate small laboratories such as wastewater operations. Such laboratories would not be able to list themselves as NELAP-approved.

A question was asked regarding the reasons why small laboratories feel they cannot meet the requirements of the NELAC Standards. Participants felt that some laboratories have problems with staff not meeting NELAC personnel qualification requirements while others may lack quality system manuals, etc. Many stated that the potential costs of NELAP accreditation are a legitimate issue for the small laboratory. However, many felt that small laboratories are simply ignorant of NELAC and its requirements. One participant spoke of the positive response to NELAP generated by an informal outreach program provided to small laboratories in Colorado.

## **ACCREDITING AUTHORITIES - SECOND ROUND OF APPROVALS**

The committee then discussed events anticipated to follow EPA's evaluation of the initial group of 18 States. Originally, it was planned that all States applying for NELAP recognition after this initial group would also be grouped and evaluated at the same time. Participants were informed that the plan has been modified so that those later States will now be evaluated on a first-come, first-served basis.

A participant asked whether a State could apply for NELAP accreditation on a program-by-program basis. States will be allowed to do this but will be encouraged to apply for as many programs at one time as possible. There was concern that this piecemeal approval might have implications regarding mutual recognition among accrediting authorities. While it was agreed that

“mutual” recognition would work for programs existing in both States, it was agreed that simple recognition without the mutual connotation would be more appropriate.

States submitting NELAP applications after the January 31, 1998, deadline will be placed on a waiting list and reviewed on a first-come, first-served basis. The waiting list is necessary so that the proposed time frame for the review/approval of the initial group of applications can be honored.

## **OTHER TOPICS AND INPUT FROM PARTICIPANTS**

It was agreed that a primary accrediting authority may elect to refuse to accept out-of-state applications. It was thought that there will be enough States among the initial 18 willing to perform out-of-state inspections so that any laboratory that needs to apply to a State other than its own will be able to do so.

A participant asked if a secondary accrediting authority with supplemental requirements can replicate any function of the laboratory’s primary accrediting authority. The committee responded that no replication of a primary accreditation authority’s functions by a secondary accrediting authority would be allowed.

Guidance was sought for the proper course of action to be taken when a secondary accrediting authority suspects a problem with a laboratory’s data, and specifically whether the secondary accrediting authority could inspect the subject laboratory. It was agreed that the secondary accrediting authority cannot conduct an inspection but must take its concerns to the primary accrediting authority. If the secondary accrediting authority is at that point not satisfied with the response of the primary accrediting authority, the secondary accrediting authority would then be allowed to direct its concerns to the NELAC Director. If the primary accrediting authority is determined not to have handled the appeal appropriately, it may lose its own NELAP recognition.

**ACTION ITEMS**  
**Transition Committee**  
**January 15, 1998**

<b>Item No.</b>	<b>Action Item</b>	<b>Date To Be Completed</b>
1.	Recommend that applications received from states after January 31, 1998, be processed in the order in which they are received. Priority will be given to those applications received by January 31.	
2.	Recommend that the NELAC Board of Directors adopt a resolution replacing the word "reciprocity" with "recognition" wherever the former appears in the NELAC Standards.	
3.	Recommend that, within the context of NELAP only, the term "non-NELAP" be applied to any laboratory program that is not NELAP-recognized.	
4.	<p>Recommend that, prior to July 1, 2000, any new accrediting authority seeking NELAP recognition have two years to correct any deficiency that requires legislation or rule-making to bring its program into compliance with NELAP.</p> <p>Further recommend that, after July 1, 2000, any new accrediting authority coming into the program be fully compliant with NELAC Standards as of the date of their approval.</p> <p>Further recommend that, after July 1, 2000, accrediting authorities have two years to make any changes that are necessary as a result of changes made to NELAC Standards.</p>	
5.	Consider the need for review and oversight of assessor training.	

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**January 15, 1998**

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